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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,805	03/26/2007	Menachem Rubinstein	30694/42147	8352

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
07/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,805	RUBINSTEIN ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 31-33, and claims 34-36 in part, drawn to a pharmaceutical composition comprising an antagonist/inhibitor of IL-1 and IL-18BP.

Group II, claim(s) 34 in part, drawn to a pharmaceutical composition comprising an expression vector encoding an IL-1 antagonist/inhibitor and an expression vector encoding IL- 18BP.

Group III, claim(s) 35 in part, drawn to a pharmaceutical composition comprising with a vector for inducing and/or enhancing the endogenous production of an IL-1 antagonist/inhibitor, and a vector for inducing and/or enhancing the endogenous production of IL-18BP in a cell.

Group IV, claim(s) 36 in part, drawn to a pharmaceutical composition comprising a cell genetically modified to produce an IL-1 antagonist/inhibitor or to produce IL-18BP.

Group V, claim(s) 37-40, 41 in part, 42-60, 61 in part, 63-64 in part, 65, 66, and 67 in part, drawn to a method of treatment of inflammatory disease with IL-18BP and an IL-1 antagonist/inhibitor.

Group VI, claim(s) 41 and 67 in part, drawn to a method of treatment of inflammatory disease with IL-18BP and an IL-1 antagonist/inhibitor, wherein the IL-1 antagonist/inhibitor is antisense mRNA.

Group VII, claim(s) 61 in part and claim 62, drawn to a method of treatment of inflammatory disease with an expression vector encoding an IL-1 antagonist/inhibitor and an expression vector encoding IL- 18BP (gene therapy).

Group VIII, claim(s) 63 in part, 65 and 66, drawn to a method of treatment of inflammatory disease with a vector for inducing and/or enhancing the endogenous production of an IL-1 antagonist/inhibitor, and a vector for inducing and/or enhancing the endogenous production of IL-18BP in a cell.

Group IX, claim(s) 64 in part, 65 and 66, drawn to a method of treatment of inflammatory disease with a cell genetically modified to produce an IL-1 antagonist/inhibitor or to produce IL-18BP.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R., the main invention in the instant application comprises the invention first mentioned in the claims, that is a pharmaceutical composition comprising an antagonist/inhibitor of IL-1 and IL-18BP. Groups II-IV inventions are directed to products with distinct chemical entities from that of the main invention. As such, they do not share a special technical feature with the main invention within the meaning of PCT Rule 13.2, and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1. Further, although Group V is directed to a method of using IL-18BP and an antagonist/inhibitor of IL-1, the products are not an advance over the prior art. It is apparent that Sims et al. (US 2002/0098185 A1) discloses antagonists of IL-18, including, among others, IL-18BP (abstract). Additionally, Sims teaches an IL-18 antagonist can be used in combination with an IL-1 antagonist for disease treatment (page 6, [0052], the last four lines of 1st column). Therefore, the ref renders claim 1, among the other, not novel. Thus the technical feature of the composition is not special and the groups (V and the main invention) are not so linked under PCT Rule 13.1. The additional methods of Groups VI-IX inventions do not relate to a single inventive concept with the main invention under PCT Rule 13.1 because, under PCT Rule 13.2, and they lack the same technical feature as they are neither methods of making nor methods of using the product of the main invention.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1): ICE inhibitors;

2): antibodies against IL-1;

3): antibodies against any of the IL-1 receptor subunits;

4): inhibitors of the IL-1 signaling pathway;

5): antagonists of lL-1 competing with IL-1 and blocking the IL-1 receptor;

6): IL-1 binding proteins;

7): IL-1Ra; and

8): soluble IL-1R.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 38: species 1)-6)
Claim 39: species 7),
Claim 41: species 3) and 8)

The following claim(s) are generic: claim 37.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The IL-1 antagonists/inhibitors set forth above are unrelated, each to each other, as they are structurally and/or functionally distinct chemical entities. Therefore, they do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DONG JIANG whose telephone number is (571)272-0872. The examiner can normally be reached on 9:30 am - 7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Patent Examiner, Art Unit 1646
7/18/08